Rhonda Jones

Regulatory Comments on:

EPA Protocol for the Evaluation of Bactericidal Activity of Hard, Non-Porous Copper/Copper-Alloy Surfaces (9-19-14)

1. Is the intent of the protocol to be applicable only for copper as stated throughout in the title and scope or is it meant for all "solid non-food contact surfaces" as stated on page 1?
    a. Why is this specific for non-food contact? How would the protocol be different for food contact?
2. This protocol is written in a manner that suggests the surface will be permanently installed. How will products that are not installed but have a shorter life span (i.e. 6 months or 24 hours) be regulated?
3. The caveats mentioned on page 1, overview section, paragraph II that specify, indoor use only for non-porous substrates, should be reflected within the title.
4. This abrasion cycle requires an unreasonable amount of personnel time. This would require, at a minimum, a full time dedicated resource for the entire 12 week cycles for sample prep alone. What is the rationale behind this exposure and treatment regimen?
    a. Would an alternative protocol that allow 18 consecutive passes followed by a 30 minute exposure to the chemical performed each day for twelve weeks be allowed (no alternating)?
    b. Would it be possible to run all scrub cycles at once (1080 passes) followed by one long chemical exposure (30 hour)?
5. Will alternate contact times be acceptable? < 1 hour Or > 1 hour if the claim is adjusted accordingly.
6. Why are there no stainless steel carriers exposed to the same abrasion and chemicals? Surfaces that are abraded have different surface energies and therefore different characteristics that can impact efficacy. In addition, it is possible that the active ingredient from the chemical treatment will build up and that is not seen without the appropriate controls. In summary, without controls that have been physically abraded or chemically treated there is no comparison.
7. Provide additional specificity about a shortened time frame. For example, if the last solution is applied to the surface for 10 minutes, allowed to dry and then the final test conducted within 30 minutes the results may be different than those obtained if the surface is tested 2 weeks after the final treatment.
8. How are visual changes qualified? There is no specificity for qualifying any visual change to the surface. Will a registration be rejected if an aesthetic change is noted? If so, define the limit for a pass/fail criterion.
9. If a registrant specifically states a cleaner or concentration, can the chemical treatments be replaced or substituted for a customized cleaner or blend?
10. If a registrant states on the label that a specific cleaner is not to be used (i.e. "Do not use bleach") how will that be handled by the agency with this protocol?
11. Please include a table that defines the timing of each step.
12. Page 4 solution A specifies that the final concentration of the solution should be verified and recorded. Please specify a method
13. Page 5 Solution C. How is this solution verified?

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14. For the wear tester, please specify the exact setup. Is it the same as specified in the EPA 01-1A Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces?
15. How often is the Scotch Brite pad changed?
16. For the application of the chemical treatment:
    a. Specify a bottle and sprayer type, # of pumps, distance to be utilized for the sprayer
    b. Alternatively, specify a volume to pipette onto the surface for reproducibility
17. On page 6 step 3
    a. Define a "suitable detergent solution". Please include concentrations.
    b. "Should result in a surface free of residual detergent without any residual antimicrobial properties" How is this to be tested and differentiated from the inherent antimicrobial properties of the surface?
18. On page 6, step 4 "place face up on matted, pre-sterilized petri dishes". What does this mean, please provide additional details.
19. Please add the control carriers to the actual count of samples reflected in Table 2. i.e. the sterility control carriers need to be included in the total sample #
20. The preparation of test cultures is outdated and needs to be revised to current microbiological techniques.
21. On page 7, step 3
    a. These are 2 very different techniques and could result in differing nutrient concentrations/organism. Please provide a definitive way to prepare the organism, i.e. spectrophotometry at OD_{600}, this is an AOAC accepted technique (?). If this is the test following 12 weeks of cycles, there should be a definitive way to prep the culture that does not allow for to day to day variation in concentration.
22. What is the target concentration for the starting inoculum (2 x 10^4 is specified to be recovered)?
23. A higher concentration of detergent (0.05%) would be needed with polymeric surfaces that are hydrophobic in nature.
24. Specify that neutralization must be confirmed prior to testing initiation and should be reported separately.
25. Page 9, part F, step 3. "Hold the carrier in the neutralizing solution for approximately 10 minutes." The method calls for 5 minutes of sonicating before plating. Why is the neutralization study doubling the neutralization time?
26. Page 8, step 11 and Page 9, enumeration techniques. There are AOAC approved most probable number systems. Can these be utilized in place of standard plate count techniques?
27. Page 11, if this is applicable to other surfaces the active ingredient should not be specified in the supported claims within the method.
28. Page 11 part 1. Change "Heath care" to "Health care"
29. Are all organisms required for a claim or is it permissible to select organisms based on use site?

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30. Has the EPA or a 3rd party lab conducted this testing? If so please provide repeatability and reproducibility for the protocol.